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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/628,387	08/01/2000	Patrick Soon-Shiong	ABI1150-18	5713

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EXAMINER
PULLIAM, AMY E

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 05/20/2002 12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/628,387	Applicant(s) <UNKNOWN>	
	Examin r Amy E Pulliam	Art Unit 1615	

-- The MAILING DATE of this communication app ars on th cover sh et with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 March 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16, 30-44, 58-78, 98-101, 104-107, 110-113, 116-119, 122-125, 128-131, 133-135, 137-141, 145-147, 149-151, 153-158, 160-162, and 164-177* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Continuation of Disposition of Claims: Claims pending in the application are 1-16,30-44,58-78,98-101,104-107,110-113,116-119,122-125,128-131,133-135,137-141,145-147,149-151,153-158,160-162 and 164-177.

DETAILED ACTION

Receipt is acknowledged of the request for an RCE, the Prior Art, and the Preliminary Amendment B, received March 7, 2002.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-16, 30-44, 58-78, 98-101, 104-107, 110-113, 116-119, 122-125, 128-131, 133-135, 137-141, 145-147, 149-151, 153-158, 160-162, 164-177 remain rejected under the judicially created doctrine of double patenting over claims 1-57 of U. S. Patent No. 6,096,331 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: a unit dosage form comprising a taxane for systemic administration.

Claims 1-16, 30-44, 58-78, 98-101, 104-107, 110-113, 116-119, 122, 125, 128-131, 133-135, 137-141, 145-147, 149-151, 153-158, 160-162, 164-166, 168, and 170 remain provisionally rejected under the judicially created doctrine of double patenting over claims 1-78 of copending Application No. 09/628,389. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: a unit dosage form comprising a taxane for systemic adminstration.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-16, 30-44, 58-78, 98-101, 104-107, 110-113, 116-119, 122-125, 128-131, 133-135, 137-141, 145-147, 149-151, 153-158, 160-162, 164-177 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Elements which are critical or essential to the practice of the invention, but not included in the claim(s) are not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

At page 11 of the instant specification, applicant teaches "in accordance with the present invention, there are provided compositions and methods useful for in vivo delivery of biologics, in the form of nanoparticles that are suitable for parenteral administration in aqueous

suspension. [The] invention compositions comprise drugs, such as paclitaxel, stabilized by a polymer. The polymer is a biocompatible material, such as the protein albumin." Applicant has defined their invention in this paragraph broadly to include nanoparticles of the specific drug, stabilized by a polymer, and suspended in an aqueous solution for parenteral administration, however, none of these defining elements are found in the claim. Additionally, at page 12, l 12-13, applicant states that it is very surprising that the invention formulation of paclitaxel, Capxol, a nanoparticle formulation, concentrates in tissues. Further, at lines 24-30 states that the basis for the unexpected results (localization within the prostate) could be a result of the specific particle size of the formulation (20-400 nm), or the presence of the protein albumin in the formulation. Again, it appears that the unexpected results of applicant's claimed invention are at least in part due to the formulation being nanoparticles, and the formulation comprising albumin, however, neither of these limitations are recited in the claims. Based on the disclosures in the specification, applicant's invention appears to be a composition known as Capxol™, which is a lyophilized powder, with a particular particle size range, containing paclitaxel and human serum albumin. Applicant has omitted essential elements from the claims, and appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-14, 16, 30-42, 44, 58-76, 78, 98, 99, 101, 104, 105, 107, 110, 111, 113, 116, 117, 119, 122, 123, 125, 128, 129, 131, 133, 135, 137-139, 141, 145, 147, 149, 151, 153-154, 156, 158, 160, 162, 164-168, 170, and 172-177 are rejected under 35 U.S.C. 102(b) as being unpatentable over pages 2780-2785 of the 1994 edition of Drug Facts and Comparisons.

Drugs, Facts and Comparisons teaches that on December 29, 1992, the FDA approved paclitaxel for treatment. Further, the reference shows that the formulations which were approved are 135 mg/m^2 or 175 mg/m^2, administered intravenously over three hours every three weeks. This disclosure alone suggests applicants claimed formulations and methods.

However, applicant has amended the claims to include the unit dosage form in a sealed vial. The examiner points to the bottom of page 2785, which shows that paclitaxel is stored in single dose vials. This disclosure anticipates the new limitation to applicant's claims.

Applicant argues that the reference does not teach unit dosage forms, or describe single doses containing taxane in the range of about 30mg/m^2 to about 1000 mg/m^2. The examiner respectfully disagrees. The reference clearly teaches a single dosage of a taxane, in the amount of 135 mg/m^2 or 175 mg/m^2, to be administered over a three hour period. Applicant is asserting that there is a blatant difference between this reference and a unit dosage form, but it is the position of the examiner that the teaching of the reference *is* a unit dosage form, specifically in light of the teaching at the bottom of page 2785, which states paclitaxel is stored in single dose vials. Furthermore, it is the position of the examiner that a teaching to a single dosage form is

the equivalent of a teaching to the recommended quantity of drug to be administered to a subject. In both instances, the teaching would disclose the specific amount of drug to be included in a formulation, which would be administered to a patient at one sitting.

Claims 1-15, 30-43, 58-77, 98-100, 104-106, 110-112, 116-118, 122-124, 128-130, 133-134, 137-140, 145-146, 149-150, 153-157, 160-161, 164-171, and 177 are rejected under 35 U.S.C. 102(b) as being anticipated by page 3558 of Drug Facts and Comparisons. This reference teaches that on May 14, 1996 the FDA approved docetaxel for treatment. Further, the reference shows that the formulations which were approved are 60 mg/m^2 to 100 mg/m^2, administered intravenously over an hour every three weeks. This disclosure directly anticipates applicants claimed formulations and methods.

However, applicant has amended the claims to include the unit dosage form in a sealed vial. The examiner points to the bottom of page3558, which shows that docetaxel is stored in single dose vials. This disclosure anticipates the new limitation to applicant's claims.

Applicant argues that the reference does not teach unit dosage forms, or describe single doses containing docetaxel in the range of about 40mg/m^2 to about 800 mg/m^2. The examiner respectfully disagrees. The reference clearly teaches a single dosage of docetaxel, in the amount of 60 mg/m^2 to 100 mg/m^2, to be administered over a one hour period. Applicant is asserting that there is a blatant difference between this reference and a unit dosage form, but it is the position of the examiner that the teaching of the reference *is* a unit dosage form. Furthermore, it is the position of the examiner that a teaching to a single dosage form is the equivalent of a

teaching to the recommended quantity of drug to be administered to a subject. In both instances, the teaching would disclose the specific amount of drug to be included in a formulation, which would be administered to a patient at one sitting. For these reasons, this rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-16, 30-44, 58-78, 98-101, 104-107, 110-113, 116-119, 122-125, 128-131, 133-135, 137-141, 145-147, 149-151, 153-158, 160-162, and 164-177 are rejected under 35 U.S.C. 103(a) as being unpatentable over pages 2780-2785 or page 3558 of Drug Facts and Comparisons as applied above. The reference does not specifically state the mg amounts as claimed by applicant in claims 58 –78. However, the reference does teach the same concentration amounts, thereby implying that the dosages contain the same amounts, especially as they are used for the same purpose, over the same period of time. One of ordinary skill in the art would have been motivated to make a pharmaceutical formulation of a taxane, either paclitaxel or docetaxel, based on the disclosure in Drug Facts and Comparisons, as the formulations claimed by applicant are taught in the reference for each of these drugs. The expected result would be a successful antitumor formulation. Therefore, this invention as a

whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Applicant argues that their invention distinguishes over the references by requiring unit dosage forms comprising a contained containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2 over an administration period no greater than about three hours. The examiner repeats the response to the 102 rejections, as stated above. Furthermore, this argument is considered moot, due to the teachings of single dose vials, found in the reference.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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